

In re Application of: GIBBINS, Bruce et al.
Serial No.: 09/752,939
Response to Office Action

REMARKS

Claims 1, 2, 4, 6, 8, 21-28, 31-35, 38, and 39 are pending in the application, and with entry of this Response, Claims 1, 6, 8, 21, 38, and 39 are amended, and Claims 40-71 are new. The amendments to the claims are supported by the application as originally filed and do not introduce new matter. Applicants respectfully submit that support for amendments to Claims 1, 38, and 39 can be found in the specification as originally filed at least at page 17, line 16 – page 18, line 8; page 20, line 8 – page 21, line 15; page 26, line 10 – line 28; page 43, line 27 – page 44, line 14; and page 47, line 11 – page 48, line 16. Applicants respectfully submit that support for amendments to Claim 6 can be found at least at page 21, line 16 – page 22, line 3. Applicants respectfully submit that support for amendments to Claim 8 can be found at least at page 21, lines 20-22.

WITHDRAWAL OF CLAIM 39 FROM CONSIDERATION

The Examiner withdrew Claim 39 from consideration as being directed to a non-elected invention. The Examiner withdrew Claim 39 because Claim 39 did “not require oxygen to be generated from the reaction of a catalyst and a reactant.” Applicants traverse this finding and request reconsideration and withdrawal of the restriction of the claims. In the almost eight years of examination of this application, the recitation of oxygen being generated from the reaction of a catalyst and a reactant was not recited, and it was not added until the last Response, filed October 9, 2007. Applicants have amended Claim 39 to recite that oxygen results from the reaction of a catalyst and a reactant and request that the restriction be reconsidered in view of the amendment and be withdrawn.

REJECTION OF CLAIMS 1, 2, 4, 6, 8, 21-28, 31-35, AND 38 UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 1, 2, 4, 6, 8, 21-28, 31-35, and 38 were rejected by the Examiner under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner rejected Claims 1, 2, 4, 6, 8, 21-28, 31-35, and 38 for failing to comply with the written description requirement as the phrases “ ‘catalyst dispersed in the matrix’, ‘substantially

In re Application of: GIBBINS, Bruce et al.
Serial No.: 09/752,939
Response to Office Action

where the catalyst is present', and 'catalyst generating oxygen' [are] new matter that has not been disclosed by the specification as originally filed." Applicants traverse this rejection.

In order to facilitate prosecution, Applicants have amended the claims and respectfully submit that the rejection is overcome in part in view of the present amendments, and that support for these amendments can be found in the application as filed, as noted in the Remarks section. Applicants submit that the phrase "substantially where the catalyst is present" is supported by the application as filed.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. *See, e.g., Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991); *see also* MPEP § 2163. Furthermore, "the subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement." MPEP § 2163.02.

Applicants submit that the application as filed teaches a catalyst mixed within a polyacrylamide matrix in at least at page 20, line 8 – page 22, line 3. The application as filed teaches the reaction of a catalyst and second reactant, which results in the decomposition of the second reactant to produce oxygen, and the oxygen, trapped by the cross-linked polyacrylamide, forms closed cells or bubbles in the polyacrylamide matrix, see at least page 21, lines 10-15. Considering that oxygen is produced by the reaction of the second reactant with the catalyst and that the catalyst is fixed within the cross-linked polyacrylamide network, one of skill in the art would reasonably conclude that oxygen will be found in the polyacrylamide network substantially where the catalyst is present. Thus, one of ordinary skill in the art one skilled in the art would reasonably conclude that the inventor had possession of the invention having "oxygen in closed cells within the cross-linked polyacrylamide polymer network substantially where the catalyst is present." Applicants respectfully request the Examiner to withdraw this rejection.

The Examiner stated that "the expression 'reactant' is broad and encompasses myriad of reactant, and applicants did not disclose any second reactant other than hydrogen peroxide. . . ." Applicants traverse this rejection. Applicants respectfully submit that support for the term

In re Application of: GIBBINS, Bruce et al.
Serial No.: 09/752,939
Response to Office Action

"second reactant" can be found in at least page 21, line 16 – page 22, line 3. Thus, Applicants respectfully request the Examiner to withdraw this rejection.

The Examiner also stated that "claims 21 and 22 recite the following elements as active agents in the matrix: herbicides, indicator of change in the environment, sera, nucleic acid, nucleosides, amino acids, and noble gases. It is not described in the specification how such elements act as active agents in terms of treating compromised tissues including wound dressing." Applicants traverse this rejection. Applicants respectfully submit that the currently claimed invention is not limited to a "wound dressing," as the Examiner states. In contrast, Applicants submit that the invention is a matrix that delivers gases, such as oxygen, and can be used in applications where gas delivery is useful. For illustration, see at least Examples 3, 6, and 7, and page 40, line 6 – page 42, line 15. Matrices delivering gas may have active agents that are beneficial to the particular application and the active agents may include at least the active agents currently claimed and their equivalents. Applicants respectfully request the Examiner to withdraw this rejection.

REJECTION OF CLAIMS 1, 2, 4, 6, 8, 21-28, AND 31-35 UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 1, 2, 4, 6, 8, 21-28, and 31-35 were rejected by the Examiner under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner rejected Claims 1, 2, 4, 6, 8, 21-28, 31, -35, and 38 "as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." The Examiner states that the "claims . . . recit[ing] 'oxygen in closed cells in the cross-linked matrix substantially where the catalyst is present' . . . is ambiguous." Applicants traverse this rejection.

Applicants submit that the word "substantially" is definite. Applicants submit that "[t]he fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. [§] 112, second paragraph." Seattle Box Co., v. Industrial Crating & Packing, Inc., 731 F.2d 818 (Fed. Cir. 1984). Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification. See, MPEP § 2173.05(b). The Federal Circuit has held that the term

In re Application of: GIBBINS, Bruce et al.
Serial No.: 09/752,939
Response to Office Action

"substantially" is definite. *See e.g., In re Mattison*, 509 F.2d 563 (CCPA 1975); *Andrew Corp. v. Gabriel Electronics*, 847 F.2d 819 (Fed. Cir. 1988); *see also*, MPEP § 2173.05(b). One of ordinary skill in the art would understand that "oxygen in closed cells within the cross-linked polyacrylamide polymer network substantially where the catalyst is present" results from the production of oxygen by the reaction of the catalyst and the second reactant, and the entrapment of at least a portion of the oxygen in closed bubbles formed from the cross-linked polyacrylamide. Considering that oxygen is produced by the reaction of the second reactant with the catalyst and the catalyst is fixed within the cross-linked polyacrylamide network, one of skill in the art would understand that a good portion of the oxygen produced would be found in the polyacrylamide network where the catalyst is present. *See*, Applicants' Specification, page 21, lines 10-15. The cross-linked polyacrylamide polymer network is hydrated, and one of ordinary skill in the art would understand that some oxygen may dissolve in the hydrated polyacrylamide network, even though a good portion of the oxygen produced would be constrained by the cross-linked polyacrylamide matrix and form bubbles or closed cells in the cross-linked polyacrylamide network. Therefore, use of the word "substantially" is both definite and appropriate in the currently pending claims. As a result, Applicants respectfully request the Examiner to withdraw this rejection.

The Examiner also states that the phrase "antifungal agents, anti-bacterial agents, anti-viral agents, anti-parasitic agents" in Claim 21 is repetitive. Applicants submit that Claim 21 has been amended to omit this repetition and respectfully request the Examiner to withdraw this rejection.

REJECTION OF CLAIMS 1, 2, 4, 6, 8, 21-28, 31-35, AND 38 UNDER 35 U.S.C. § 103(a)

Claims 1, 2, 4, 6, 8, 21-28, 31-35, and 38 were rejected by the Examiner under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application Publication 2002/0042587 to Murdock (hereinafter, "the '587 publication") in view of U.S. Patent No. 5,792,090 to Ladin (hereinafter, "the '090 patent"). Citations herein are to the published application and patent documents. The Examiner stated that "it would have been obvious to one having ordinary skill in the art at the time of the invention to provide polymeric cross-linked closed cell foam that can

In re Application of: GIBBINS, Bruce et al.
Serial No.: 09/752,939
Response to Office Action

be produced chemically as disclosed by US '587, and produce the foam by oxygen gas delivered by the reaction of hydrogen peroxide and catalyst and replace the polymer by polyacrylamide as disclosed by US '090, motivated by the teaching of US '090 that such polyacrylamide polymer foam containing oxygen are optimal for minimization of infection, with reasonable expectation of having polyacrylamide cross-linked closed cell foam entrapping oxygen produced chemically by the reaction of hydrogen peroxide and catalyst with minimal infection to the underlying skin." Applicants respectfully traverse this rejection.

The Examiner stated that the '587 publication "teaches a polymeric cross-linked foam reservoir comprising cellulose derivatives and active agent including anti-infective agents and growth factors. The foam reservoir is [a] closed cell foam that can be produced chemically and contains gasses including oxygen." The Examiner admits that the '587 publication, however, "does not teach the chemical reaction that produces the gas in the foam . . . [or a] polyacrylamide polymer."

Applicants submit that the '587 publication teaches "foaming a polymeric solution", and not foaming a cross-linked polymeric network. (§ 32 and 36). The '587 publication teaches the formation of a foamed polymeric solution "by extrusion spraying, frothing, compression molding, injection molding, sintering, leaching, or the like. Foam formation may be accomplished by stirring a polymer solution with a high speed, high sheer mixing apparatus and or by an apparatus that injects gas into a solution of the polymer." (§ 36). The '587 publication also teaches preparation of "a foamed polymer [solution] . . . by decompression expansion [, wherein] a solution of a volatile blowing agent in molten polymer is formed in an extruder under pressure." (§ 38). The '587 publication also teaches a foam that can be made by a "frothing process[, which] involves dispersing a gas in a fluid that has surface properties suitable for producing a foam. After formation of the foam, it can be permanently stabilized by crosslinking." (§ 39). The '587 publication teaches the "dimensional stability [of the polymer solution with the incorporated gas] is achieved upon cooling or other cross-linking methods." (§ 38). Therefore, in the embodiments taught by the '587 publication, the gas of the polymer matrix in the '587 publication is introduced into the composition when the polymer solution is a liquid, and before the polymer solution is cross-linked.

In re Application of: GIBBINS, Bruce et al.
Serial No.: 09/752,939
Response to Office Action

Considering that the '587 publication teaches the introduction of a gas into a polymer solution prior to cross-linking the polymer matrix, the '587 publication does not teach or suggest the present invention. The Examiner acknowledges that the '587 publication "does not teach polyacrylamide polymer as claimed [in the present application]." However, the Examiner suggests that the polymer of the '587 publication can be "replace[d with] the polymer polyacrylamide as disclosed by US '090." Applicants respectfully submit that there is no suggestion or motivation to make the proposed modification.

Applicants are not arguing for a rigid application of the teaching-suggestion-motivation (TSM) rationale, which requires that a printed statement to be present for a finding of obviousness. Instead, Applicants submit that the Supreme Court acknowledged that the TSM test was one of a number of valid rationales that could be used to determine obviousness. KSR Int'l Co. v. Teleflex, Inc., 127 S. Ct. 1727 (2007); see MPEP § 2141; In re Kahn, 441 F.3d 977, 986, 78 U.S.P.Q. 2d 1329, 1335 (Fed. Cir. 2006). Applicants respectfully submit that there is no suggestion or motivation to make the proposed modification of a polyacrylamide polymer of the '090 patent in the foam of the '587 publication, and in fact, the '587 publication teaches away from use of polyacrylamide by requiring the gas be introduced into a liquid polymer solution prior to the cross-linking of the polymer solution.

Modification of the '587 publication by implementation of polyacrylamide polymer to create a polyacrylamide foam matrix as taught in the '587 publication would render the '587 publication unsatisfactory for its intended purpose. According to the U.S. Court of Appeals for the Federal Circuit, "[i]f [the] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed invention." (In re Gordon, 733 F.2d 900, 221 U.S.P.Q. 125 (Fed. Cir. 1984); see MPEP § 2143.01). Attempts to create a foam matrix by the methods disclosed in the '587 publication with polyacrylamide, as taught in the '090 patent, would result in a foam composition unsatisfactory for its intended purpose. More specifically, formation of a foam made from polyacrylamide by the methods of the '587 publication would result in the formation of a liquid gelatinous mass.

In re Application of: GIBBINS, Bruce et al.
Serial No.: 09/752,939
Response to Office Action

According to the teaching of the '587 publication, a polymer is mixed in a solution, a gas is introduced into the polymer mixture, and the polymer mixture with the incorporated gas are cross-linked to form a foam matrix. Using this method of the '587 publication, in view of the '090 patent, if polyacrylamide polymer was mixed in a solution, then oxygen was introduced into the polyacrylamide polymer solution, and the polyacrylamide polymer mixture with the incorporated gas were attempted to be cross-linked, the polyacrylamide would not cross-link because oxygen retards the polymerization of polyacrylamide, and a poorly-cross-linked, (if any cross-linking would occur), liquid gelatinous mass may result.

It is well known in the art that polyacrylamide does not sufficiently polymerize in the presence of oxygen. Diffusion of atmospheric oxygen into a polyacrylamide solution can detrimentally affect the cross-linking of polyacrylamide polymers. (Sambrook and Russell, Molecular Cloning: A Laboratory Manual, Vol. 3, p. A8.44 –45 (copy attached as Exhibit 1). As shown in this protocol, the polyacrylamide solution is protected from exposure to atmospheric air (which is approximately 20% oxygen) so as to eliminate the amount of oxygen contacting the polyacrylamide solution. (*Id.*) The protocol also refers to de-gassing, which is a common step used for removing gases from an initial solution of acrylamide polymers to prevent the interference by oxygen in the polymerization reaction. (*Id.*) Considering the inability to cross-link polyacrylamide in the presence of oxygen, a person of ordinary skill in the art would not be motivated to intentionally introduce oxygen, according to the teaching of the '587 publication, to a polyacrylamide solution, and not at any time while the polyacrylamide solution is liquid.

Furthermore, the detrimental effect of the presence of oxygen in a polyacrylamide solution would result in the retardation of the polyacrylamide cross-linking and the formation of a poorly cross-linked, if any cross-linking would occur, liquid, gelatinous mass. This liquid, gelatinous mass would not function in a satisfactory fashion for its intended purpose, and not as a drug delivery matrix of the '587 publication. Attempts to create a foam matrix by the methods disclosed in the '587 publication with polyacrylamide as taught in the '090 patent would result in a foam composition unsatisfactory for its intended purpose, and thus, no suggestion or

In re Application of: GIBBINS, Bruce et al.
Serial No.: 09/752,939
Response to Office Action

motivation exists to make the proposed invention. As a result, Applicants respectfully request the Examiner to withdraw this rejection.

Formation of an oxygen-containing polyacrylamide matrix occurs if the polyacrylamide matrix is first cross-linked, and oxygen is introduced into the matrix following cross-linking of the polyacrylamide polymers. Applicants submit that the presently claimed invention is patentable over the cited prior art. The Examiner, in citing MPEP § 2113, relies exclusively the first portion of MPEP § 2113, citing In re Thorpe for stating the proposition that:

even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. 777 F.2d 695, 698 (Fed. Cir. 1985).

However, it is the remainder of MPEP § 2113 that is applicable to the presently pending claims. According to MPEP § 2113, In re Garnero states that “[t]he structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, *especially where the product can only be defined by the process steps by which the product is made*, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. 412 F.2d 276, 279 (C.C.P.A. 1979) (emphasis added); See MPEP § 2113. In the case where the polymeric matrix comprises polyacrylamide, the step of cross-linking must occur prior to the addition of oxygen, and a teaching of gas incorporation prior to cross-linking is not relevant.

The Examiner stated that “cross linking of the polymer matrix before or after addition of oxygen does not impart patentability to the claims because it has been held that it is *prima facie* obvious to reverse the order of the prior art process steps . . . selection of any order of mixing ingredients is *prima facie* obvious. Applicants failed to show superior and unexpected results obtained from cross-linking before forming oxygen or after forming oxygen in the matrix.” Applicants have repeatedly argued that an oxygen-containing polyacrylamide matrix cannot be formed if oxygen is added to a liquid polyacrylamide solution. It is well known in the art that

In re Application of: GIBBINS, Bruce et al.
Serial No.: 09/752,939
Response to Office Action

polyacrylamide does not sufficiently polymerize in the presence of oxygen. It is not *prima facie* obvious to reverse the steps of a method if that is the only order of the steps that results in the final product. Applicant is not reversing the order of the steps of the '587 publication, Applicant's method of cross-linking before adding oxygen is the order of steps that results in a polyacrylamide material containing oxygen. Selection of any order of mixing ingredients may be *prima facie* obvious if the order of mixing makes no difference to the final product. Without cross-linking the polyacrylamide solution first, no oxygen can be contained by the polyacrylamide matrix, because if the oxygen is added first to the polymeric solution, the next step of cross-linking will not occur. Creation of an oxygen-containing polyacrylamide matrix can only occur if the polyacrylamide matrix is first cross-linked, and oxygen is introduced into the matrix after cross-linking of the polyacrylamide polymers. Given the technical limitations associated with cross-linking polyacrylamide in the presence of oxygen, the structure implied by the process steps must be considered when assessing the patentability of the claims. There is no reason for Applicants to provide "superior and unexpected results obtained from cross-linking before forming oxygen or after forming oxygen in the matrix" because the above statements cited for supporting *prima facie* obviousness are not applicable to the currently pending invention. Without cross-linking prior to formation of oxygen, an oxygen-delivery polyacrylamide matrix is not possible. Therefore, Applicants respectfully request the Examiner to withdraw this rejection.

The '587 publication does not teach or suggest a matrix that functions to deliver oxygen. There is no teaching in the '587 publication indicating that the gas incorporated into the polymer foam matrix would transfer from the matrix. The gas in bubbles within the polymer matrix of the '587 publication is not designed to be transferred from the polymer matrix, the bubbles are designed to provide a surface area greater than an unfoamed matrix. The '587 publication teaches that the "gas bubbles act as inert filler, increasing the surface area of the matrix without introducing the drawbacks of common 'inert' fillers." (§ 37). The gas bubbles of the '587 publication are inert, meaning that they "lack[] a usual or anticipated chemical or biological action." (Merriam-Webster's Online Dictionary available at <http://www.merriam-webster.com/dictionary/inert>). The gas bubbles of the '587 publication lack a chemical or

In re Application of: GIBBINS, Bruce et al.
Serial No.: 09/752,939
Response to Office Action

biological function. According to the '587 publication, the gas bubbles are a structural feature of the polymer foam matrix of the '587 publication to increase the surface area of the foam. The transfer of gas from the polymer matrix of the '587 publication would defeat the purpose of having gas bubbles in the polymer matrix because the transfer of gas from these bubbles would result in the collapse of the bubbles and a decrease in surface area. Therefore, the transfer of gas from the bubbles of the '587 publication would contradict the structural purpose of the bubbles in the foam of the '587 publication. There is no teaching in the '587 publication that the gas can be transferred from polymer matrix. The '587 publication does not teach or suggest an oxygen-delivery matrix.

The teachings of the '090 patent do not cure the deficiencies of the '587 publication. The Examiner states that the '090 patent "is relied upon for the solely teaching of catalyst/peroxide reaction to produce oxygen in a wound dressing matrix made of polyacrylamide." Applicants respectfully submit that the only teaching of polyacrylamide in the '090 patent is an occlusive covering that provides a layer for moisture provision (Col. 4, lines 18-22) The occlusive covering is not capable of delivery of oxygen, and does not provide a teaching or suggestion of oxygen delivery. The '090 patent teaches a reservoir that, among other alternatives, "may be a sponge-like or open-celled foam of natural, synthetic or mixed natural/synthetic origin." (Col. 5 lines 59-60). However, there is no teaching or suggestion in the '090 patent of closed cells, or the entrapment of oxygen within closed cells. In addition, there is no teaching of polyacrylamide specifically for this reservoir, nor is there a teaching of closed cells containing oxygen at any site in the reference. Applicants respectfully submit that, although the '090 patent may disclose an oxygen generating wound dressing, the '090 patent does not teach or suggest a polyacrylamide matrix having oxygen in closed cells within the cross-linked polyacrylamide polymer network.

Even if there were a reason to combine only the teaching of a catalyst and reactant from the '090 patent, there is no teaching of how to form closed cells of oxygen in a polyacrylamide matrix for the delivery of oxygen by the matrix. The combination of the catalyst from the '090 patent with a liquid polymeric solution from the '587 publication being a polyacrylamide solution, followed by addition of the reactant with the catalyst/liquid polyacrylamide solution to form oxygen may result in a foamy liquid solution but it would not result in Applicants'

In re Application of: GIBBINS, Bruce et al.
Serial No.: 09/752,939
Response to Office Action

currently claimed invention. The foamy liquid solution would not cross-link and would not resemble either the device of the '587 publication, the '090 patent device or Applicants' currently claimed invention. The catalyst/reactant portion of the '090 patent cannot be combined with the teachings of the '587 publication to provide a teaching or suggestion that renders Applicants' currently claimed invention obvious. Therefore, neither the '597 patent nor the '090 patent, either individually or combined, teach or suggest the presently claimed invention. Applicants respectfully request the Examiner to withdraw this rejection.

In re Application of: GIBBINS, Bruce et al.
Serial No.: 09/752,939
Response to Office Action

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CONCLUSION

The foregoing is a complete response to the Action dated December 28, 2008. Applicants respectfully submit that at least Claims 1, 2, 4, 6, 8, 21-28, 31-35, 38, 39, and 40-71 are patentable. Early and favorable consideration is solicited.

Applicants file this response solely to facilitate prosecution. As such, Applicants reserve the right to pursue claims of broader or similar scope as originally filed in a continuation application or other application after allowance of the present application. Applicants do not concede that the current or past rejections are correct and reserve the right to challenge such rejections later in prosecution or on appeal. Accordingly, any amendment, argument, or claim cancellation is not to be construed as abandonment or disclaimer of subject matter. Because certain of the current amendments may include broadening amendments, Applicants respectfully request the Examiner to revisit any previously reviewed references cited in this Application to further ensure that the currently pending claims remain patentable over any previously reviewed references.

The Commissioner is hereby authorized to charge \$710, which includes \$650 for 26 claims in excess of the 26 claims previously paid for and \$60 for a one month extension of time, and any additional fees that may be required, or credit any overpayment, to Deposit Account No. 20-1507.

Applicants again request the refund of the fees paid April 9, 2003, of \$980 for small entity issue fee of \$650, \$300 for publication and \$30 for patent copies. Please provide the refund to Deposit Account 20-1507.

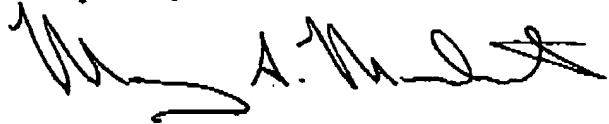
If the Examiner believes there are other issues that can be resolved by a telephone

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In re Application of. GIBBINS, Bruce et al.
Serial No.: 09/752,939
Response to Office Action

interview, or that there are any informalities that remain in the application which may be corrected by the Examiner's amendment, a telephone call to the undersigned attorney at (404) 885-3652 is respectfully solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Mary A. Merchant', with a stylized flourish at the end.

Mary Anthony Merchant, Ph.D.
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